

REMARKS

I. Amendments to the Claims:

Claims 38-57, 61-64, 66-84, 89-90, 92, and 94-100 are pending in this application.

Claims 43, 61-64, 66-84, 90, 92, and 94-98 were withdrawn from consideration.

Accordingly, claims 38-42, 44-57, 89, 99, and 100 are pending and under examination in the instant application.

Claims 38, 45, 47, 50-55, 76, 78, 89, and 100 have been amended herewith. Support for the claim amendments can be found throughout the application as filed, *inter alia*, at page 58, lines 1-3 and page 64, lines 10-26. Thus, no new matter has been added by way of the instant amendments.

Upon entry of the instant amendment to the claims, claims 38-42, 44-57, 89, 99, and 100 will be pending and under examination in the instant application.

II. Objections to the Claims:

(a) The Office Action alleges that claim 45 is a substantial duplicate of claim 44 in violation of 37 C.F.R. § 1.75(b) (*see*, Office Action, pages 3-4).

Claim 45 has been amended herewith to be dependent on claim 44. Accordingly, as the grounds for this objection have been overcome. Applicant respectfully requests that this objection be reconsidered and withdrawn.

(b) Claims 46-48 and 100 were objected to for purportedly reciting trademarks improperly (*see*, Office Action, page 4).

Claims 47 and 100 have been amended herewith to capitalize and indicate trademark status for trademarked names. Accordingly, as the grounds for this objection have been overcome, Applicant respectfully requests that this objection be reconsidered and withdrawn.

III. Rejections Under 35 U.S.C. § 112, Second Paragraph:

Claims 38-49, 56-57, 89, and 99-100 were rejected under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite. Specifically, the Office Action states that the recitation of the terms "early" and "increase in the level of the marker" are indefinite (see, Office Action, page 4).

Applicant has deleted the term "early" in claims 38 and 89, and with respect to the phrase "increase in the level of the marker," has amended claims 38 and 89 to recite, in relevant part, "increase in the level of the marker following disruption of sex steroid-mediated signaling compared with the level of the marker and the level of the TREC prior to disruption of sex steroid-mediated signaling."

Applicant submits that upon entry of the instant amendments to the claims, the grounds for this rejection has been overcome. Accordingly, Applicant respectfully requests that this rejection be reconsidered and withdrawn.

IV. Rejections Under 35 U.S.C. § 112, First Paragraph, Written Description:

Claim 57 stands rejected under 35 U.S.C. § 112, first paragraph, for purportedly failing to comply with the written description requirement (see, Office Action, pages 4-5). Specifically, the Office Action purports that no "member of the KGF family" was originally disclosed in the application. Applicant respectfully traverses this rejection.

Applicant draws the Examiner's attention to the last sentence of para. [0217] of Applicant's disclosure in US 2005/0042679 (publication of this application), which recites: "Examples of thymic cytokines include without limitation IL-7, *members of the* Fibroblast Growth Factor (FGF) and *Keratinocyte Growth Factor (KGF) families*, and chemokines." (emphasis supplied).

In view of this disclosure, Applicant respectfully submits that the grounds for this rejection have been overcome. Accordingly, Applicant respectfully requests that this rejection be reconsidered and withdrawn.

V. Rejections Under 35 U.S.C. § 103(a):

Claims 38-39, 42, 44-46, 48, 50-57, 89, and 99 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Coy et al.* (U.S. Pat. No. 5,073,624) in view of both *Fabris* and *Mocchegiani et al.* (see, Office Action, pages 5-7).

Independent claim 38 has been amended herein to recite, in relevant part, the steps of monitoring the level in the patient's blood of newly produced T cells by monitoring T Cell Receptor Excision Circles (TRECs) in addition to monitoring the level in the blood or serum of a marker associated with the activation of the thymus (thymulin), and monitoring the level in the patient's blood or serum of the marker (thymulin) and the TRECs after disruption of sex steroid signaling to the thymus, and comparing the level of the marker (thymulin) and the level of the TRECs before and after sex steroid disruption, wherein an increase in the level of the marker (thymulin) and in the level of the TRECs following disruption of sex-steroid signaling compared with the levels of the marker (thymulin) and the TRECs prior to disruption of sex-steroid signaling indicates susceptibility of the patient's thymus to reactivation. Independent claim 89 has been similarly amended herein.

The combined references do not teach all claim limitations of the claims as amended. Specifically, the combined references do not teach or suggest "monitoring the level in the patient's blood of newly produced T cells by monitoring T Cell Receptor Excision Circles (TRECs)" either before, after, or substantially at the same time as monitoring the level in the patient's blood or serum of thymulin (a marker associated with activation of the thymus). Neither do these combined references teach or suggest that an increase in the level of TRECs post sex-steroid disruption indicates susceptibility of the patient's thymus to reactivation.

Thus, because all claim limitations of claims 38 and 89 are not taught by the references cited in the Office Action, Applicant respectfully avers that the grounds for this rejection have been overcome. Likewise, as dependent claims 42, 44-46, 48, 50-57 and 77 contain all the limitations of claim 38 as amended, Applicant respectfully avers that the grounds for this

rejection have also been overcome. Accordingly, Applicant respectfully requests that this rejection be reconsidered and withdrawn.

VI. Supplemental IDS:

Applicant provides herewith a Supplemental IDS to resubmit the crossed out references in the previously submitted 1449s and to cite other co-pending applications. Applicant respectfully requests that the Examiner consider these references and forward Applicant a copy of the initialed IDS with the next Office Communication.

CONCLUSION

Upon entry of the instant amendment, claims 38-57, 61-64, 66-84, 89-90, 92, and 94-100 will be pending in this application.

Applicant petitions for a 1-month extension of time. Other than the extension fees and the fees associated with the filing of the Supplemental IDS, no additional fees are believed to be due in connection with this correspondence. However, if any fees are due, please charge such fees to our Deposit Account No. 08-0219.

If a telephone interview would advance prosecution of the application, the Examiner is encouraged to telephone the undersigned at the telephone number given below.

Respectfully submitted,

Dated: November 14, 2007



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Appl. No. 10/749,120
Atty. Docket No.: 286336.154US1/NOR-015CP2
Response to Office Action of 07/16/07

APPENDIX A

Attached is a copy of a Supplemental IDS.